

### **REMARKS**

Following entry of the present amendment, claims 1-9 and 56-59 will be pending in the present application. Claim 1 has been amended.

Claims 1-9 and 56-59 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness over U.S. Pat. No. 7,081,122 to Reiley (“the Reiley patent”) in view of WO 90/06150 to Motoda (“the Motoda patent”), in view of U.S. Pat. No. 5,500,013 to Buscemi *et al.* (“the Buscemi patent”). Applicants respectfully submit that claim 1, as amended, is not rendered obvious by the respective or combined teachings of the cited references.

According to the Office, “it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the tip of the catheter of Reiley et al. as taught by Motoda” (3/15/07 Office Action at pages 3-4) in order to provide the high-porosity tip of the present invention. Applicants respectfully submit that the Office’s conclusion is not based on any particular findings that one skilled in the art would have selected the cited references for combination; rather, all that has been provided is the Office’s bare assertion based upon the hindsight provided by Applicants’ own disclosure.

The mere fact that those skilled in the art *would have been able* to make the posited modification falls far short of establishing obviousness under Section 103. For example, M.P.E.P. § 2143.01(IV) cautions that statements describing modifications to a cited reference as being “well within the ordinary skill of the art” are not sufficient to establish a *prima facie* case of obviousness. Indeed, the level of skill in the art cannot be relied upon to provide the suggestion to modify references. *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308 (Fed. Cir. 1999). There must be some suggestion or motivation to make such modifications. *See* M.P.E.P. § 2143.01 (III).

When viewed in this context, the cited references cannot fairly be said to render Applicants’ claimed inventions obvious because there is no evidence of record demonstrating that those of ordinary skill would have been motivated to actually combine the references’ respective teachings or to do so in a way that would have produced a claimed invention.

Although the Office Action asserts “it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the tip of the catheter of Reiley et al. as taught by Motoda” (3/15/07 Office Action at pages 3-4) and that “the differences in material and form between the subject matter claimed and prior art are such that the subject matter as a whole would have been obvious” (4/18/07 Advisory Action at page 2), there is still no evidence or reasoning based on objective factors of record as to why those of ordinary skill would have had such motivation. Absent evidence or reasoning based on objective factors demonstrating that the posited modifications of the cited references would have been ones that those of ordinary skill in the art actually would have been motivated to make, the rejection of claims 1-9 and 56-59 for alleged obviousness is improper and should be withdrawn. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000) (“a showing of a suggestion, teaching, or motivation to combine the prior art references is an ‘essential component of an obviousness holding’”). *See also* MPEP § 2142 (“The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness.”); *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000) (“particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed”); *May 3, 2007 Memo from Margaret A. Focarino, Deputy Commissioner for Patent Operations, U.S. Patent Office* (“it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.”) (commenting on *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. at \_\_ (Apr. 30, 2007) (No. 04-1350)).

However, even if sufficient motivation did exist for one skilled in the art to have combined the cited references in the manner proposed by the Office, the proposed combination would not produce any claimed invention.

Claim 1 has been amended to clarify that the high-porosity tip is substantially rigid. This amendment is supported by the instant specification as filed, for example, at page 7,

paragraph [0023], which specifies that “[t]he high-porosity tips may comprise polylactic acid”; those skilled in the art can readily appreciate that components constructed from polylactic acid can be substantially rigid.

For a patent claim to be obvious from a modification or combination of the prior art, that modification or combination, when made, must provide precisely the invention of the claim. M.P.E.P. § 2143.03 (all claim limitations must be taught or suggested by the prior art); *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (same). None of the cited references, either separately or in combination, teach a kit comprising a catheter having a substantially rigid high-porosity tip. Although the Motoda patent teaches a catheter comprising a porous tip portion, this reference repeatedly emphasizes that, in clear contrast to the present invention, “said tip portion [is] more pliable than the aforementioned non-porous [catheter] tube” (Motoda patent at Abstract). *See also* Motoda patent at page 2, lines 22-23 (“the structure of said tip portion [is] more pliable than the aforementioned non-porous tube”); *id.* at page 3, lines 28-31 (“A catheter tip made according to these parameters is . . . much more pliable than non-porous PTFE [of which the catheter tube portion is constructed]”); *id.* at page 2, lines 19-20 (“a pliable tip portion is formed at one end of a non-porous PTFE tube”); *id.* at page 3, line 2 (“pliable tip part”); *id.* at page 3, lines 23-24 (“a catheter with a tip part (2) which is made pliable as a result of the aforementioned conversion to a porous structure”); *id.* at page 4, lines 30-31 (“pliable tip part”). Accordingly, the combination of the Reily patent and the Motoda patent would not provide precisely the inventions of rejected claim 1, as amended, and its dependents.

The Office further cites the Buscemi patent for the proposition that this reference teaches the use of polylactic acid. First, Applicants note that the Buscemi patent is directed to a different technical field than the claimed inventions, and should not be considered analogous art for purposes of a § 103 rejection. The field to which the Buscemi patent relates is vascular drug-eluting stents (*see, e.g.*, Buscemi at col. 4, lines 7-10), which is quite different than the field to which Applicants’ claims relate, *i.e.*, kits for delivery of restorative materials to intraosseous spaces. From at least a functional perspective, the Buscemi patent

occupies a different technical field and represents nonanalogous art, and therefore cannot properly support a rejection under § 103. M.P.E.P. § 2141.01(a).

Second, even if the Buscemi patent did represent analogous art, it would be improper to combine the Motoda patent with the Buscemi patent, since, to the extent that the modification rendered the Motoda patent's porous tip non-pliable, such modification would render the device of the Motoda patent unsatisfactory for its intended purpose. M.P.E.P. § 2143.01(V) (citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). The Motoda patent provides that the purpose of providing "tip portion [that is] more pliable than the aforementioned non-porous [catheter] tube" is to prevent damage to the interior walls of the heart or blood vessels by the tip of the catheter. *See* Motoda patent at Abstract ("As a result of the aforementioned porous tip portion being formed at one end of the aforementioned non-porous PTFE tube, damage . . . by the tip of the catheter is prevented."). *See also* Motoda patent at page 2, lines 24-27. Therefore, modification of the device of the Motoda patent with the teaching of the Buscemi patent, *i.e.*, to the extent that the tip portion thereof is rendered non-pliable would render that device unsatisfactory for its intended purpose.<sup>1</sup> As such, there cannot be said to be a proper teaching or suggestion to make the modification proposed by the Office, and a *prima facie* case of obviousness does not exist. M.P.E.P. 2143.03(V).

Accordingly, for at least these reasons, Applicants respectfully submit that the rejection of claim 1, as amended, under § 103(a) should be withdrawn. The rejection of the 2-9 and 56-59, all of which depend directly or indirectly from claim 1, should also be withdrawn. *See* M.P.E.P. § 2143.03 (dependents of nonobvious claim are also nonobvious).

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<sup>1</sup> Applicants also submit that the proposed modification of the Motoda patent with the teaching of the Buscemi patent would change the principle of operation of the Motoda patent, *i.e.*, that the use of a tip that is pliable relative to the catheter tube to which it is attached functions to prevent damage to the heart or blood vessels. M.P.E.P. § 2143.02(VI).

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**PATENT**

The Applicants submit that the foregoing represents a *bona fide* attempt to advance the present case to allowance, and that the application is now in condition therefor. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 215-568-3100.

/ John W. Caldwell /

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